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EXAMINER

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ART UNIT

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12/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

DETAILED ACTION

Receipt of IDS dated 7-1-09 and 8-3-09; and response dated 8-18-09 is acknowledged.

Claims 1-10, 12, 13 and 15-60 are pending.

Claims 11 and 14 are canceled.

Claims 5, 12, 13 and 26-60 are withdrawn as nonelected.

Claims 1-4, 6-10 and 15-25 have been considered for examination.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-10 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the following combinations: Lambert (J Applied Microbiol.) and US 5,612,045 to Syverson in view of US 3393678 to Pacini et al and US 4318404 to Cunningham OR unpatentable over Pacini et al in view of Cunningham, Lambert and Syverson OR unpatentable over Cunningham in view of Lambert, Syverson and Pacini et al.

Lambert studied the minimum inhibitory concentrations of different antimicrobial compounds against *S. aureus* and observed that phenoxyethanol and phenyl ethyl alcohol (designated as PoE and PeA respectively) are effective against *S. aureus* (abstract, page 276, col. 1, table 2, page 278, col. 2 and Discussion), even though the MICs vary with the inoculum levels. Lambert does not teach phenoxyethanol on a non-absorbent article as claimed in the instant invention.

Lambert fails to teach the claimed tampon applicator that is non-absorbent.

Syverson teaches catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by *S. Aureus* (abstract, col. 3, lines 40-60). The compounds of Syverson comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). Syverson teaches including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5).

While Syverson teaches absorbent tampons, instant claims require tampon applicator that is non-absorbent. Syverson states that the tampon may or may not have an applicator.

Pacini et al teach catamenial devices such as tampons that have antibacterial properties as well as physical lubricity (col. 1, L 8-14). Pacini teach that polymetallic pectinates can be made into films or their dispersions may be sprayed or applied to materials intended for vaginal tamponing. It is suggested that the compound may be applied to the textile fabric of a tampon or to the external surface of the tubular tampon applicator (col. 2, L 38-51) because menstrual discharges provide a favorable condition for bacterial or other microbial growth (col. 3, L 1-40).

Pacini does not teach the claimed non-absorbent applicator.

Cunningham describes a tampon and its applicator, where the tampon is made of absorbent material and the applicator is made of non-absorbent material (see claim 13 of Cunningham).

Art Unit: 1611

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Lambert and the second active agent (ether compounds) taught by Syverson, both of which are effective against *S. aureus*, in the tampon applicators (Cunningham) because both Lambert and Syverson suggests employing compounds that for inhibiting toxic shock syndrome (caused by *S. aureus*) caused by the use of tampons, and Pacini suggests that antimicrobial compounds may be employed wither in the tampon fabric itself or in the enclosure that holds tampons (tampon applicator) so as to inhibit the vaginal microbial growth during menstrual cycles.

Alternatively, Pacini does not teach the claimed compounds. However, it would have been obvious for one of an ordinary skill in the art at time of the instant invention to incorporate phenoxyethanol of Lambert and the second active agent of Syverson in the tampon or applicator of Pacini because Lambert teaches phenoxyethanol is effective against *S. aureus* and Syverson also suggests the claimed second agent for the same reason. Further a skilled artisan would have employed a non-absorbent article for the tampon applicator because Cunningham suggests non-absorbent tampon applicators Further, optimizing the amounts of ether (of Syverson) and phenoxyethanol of Lambert, with an expectation to provide the optimum inhibitory effect of *S. aureus* toxin production would have been within the scope of a skilled artisan.

Response to Arguments

2. Applicant's arguments filed 8-18-09 have been fully considered but they are not persuasive.

It is argued that the Office has failed to meet its burden of a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention, as there is no apparent reason for one skilled in the art to modify and/or combine the references to arrive at each and every limitation. It is argued that as recognized by the Supreme Court in *KSR International Co. v. Teleflex, Inc.*, while an obviousness determination is not a rigid formula, the TSH (teaching, suggestion, motivation) test captures a helpful insight: "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs [caution as to] a patent application that claims as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the [art] to combine the elements in the way the claimed new invention does." Applicants admit that phenethyl alcohol is a better inhibitor than phenoxyethanol against *S. aureus*. However, it is argued that as the Office recognizes on page 3 of the instant Office action, Lambert does not teach or suggest phenoxyethanol on a non-absorbent substrate. Further, it is argued that Lambert does not teach or suggest an effective amount of a second active ingredient in

Art Unit: 1611

combination with the first active ingredient deposited on a non-absorbent substrate, the significant aspects of Applicants' claim 1. It is argued that why would one having ordinary skill in the art is motivated to add a second active ingredient to Lambert when Lambert already teaches that phenoxyethanol has sufficient inhibitory characteristics? It is argued that although Lambert discloses six compounds, there is no suggestion to combine first and second compounds. It is argued that even if there is a motivation to combine the compounds of Lambert and Syverson, there is no motivation to include them in a non-absorbent substrate. The office's assertion that one would have been motivated to include the compounds on a non-absorbent substrate as suggested by Pacini has been traversed by applicants on the basis that Pacini is completely different from Lambert or Syverson because the former teaches polymetallic pectinates on tampon and not the first and second active ingredients of instant claims, for inhibiting exoproteins. It is argued that Syverson particularly teaches absorbent tampon. Applicants question the motivation to modify the teachings of Syverson, which already provides a means to inhibit exoprotein with an absorbent article. It is argued that absorbent and non-absorbent substrates have inherently different properties, and there is nothing in any of the cited references to suggest that the compounds of any of the cited references would be effective if used with a non-absorbent substrate (instant application at paragraph [0014]), specifically, the non-absorbent tampon applicator, which may have deposited thereon the claimed first and second active ingredients, houses the absorbent tampon. It is argued that based on the foregoing, it appears that the Office has used impermissible hindsight and reconstruction (using the Applicants'

Art Unit: 1611

claimed invention as a blueprint) for arriving at such a combination/modification. The Federal Circuit has consistently warned against this type of analysis.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the references show that the knowledge of inhibiting *S. aureus* exoproteins with various antimicrobial agents, and incorporating known antimicrobial agents on singly or in combination, in the absorbent or non-absorbent substrates that make up tampons such that the antimicrobial compounds inhibit *S. aureus* proteins is known. The question to be resolved is whether the claimed compounds are known to be employed on non-absorbent substrates (as in the instant claims). The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). In *Kubin*, the court commented that "responding to concerns about uncertainty in the prior art influencing the purported success of the claimed combination, this court

Art Unit: 1611

[in O'Farrell] stated: obviousness does not require absolute predictability of success ... all that is required is a reasonable expectation of success.'" In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (citing In re O'Farrell, 853 F.2d 894, 903-904 (Fed. Cir. 1988)).

The rejection detailed in the preceding paragraphs provides a reasonable expectation of success in inhibiting the exoproteins of *S. aureus* by including a combination of antimicrobial compounds (against *S. aureus*) in the absorbent or a non-absorbent substrate of a tampon. With respect to the arguments that Lambert does not teach combination of compounds and a non-absorbent article, Pacini teaches different compounds other than the claimed compounds, Syverson teaches an absorbent substrate and Cunningham fails to disclose depositing any antimicrobial substance, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In KSR, the Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct. Further, known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. In the instant case, the prior cited in rejecting the instant claims is not providing a general concept or requires a skilled artisan to explore a new technology and instead provides the specific teachings of inhibiting *S.aureus* with compounds that are more effective (phenoxyethanol of

Art Unit: 1611

Lambert) than others and incorporating such compounds on non-absorbent substrates of tampons (Cunningham). While applicants repeatedly argue that one cannot combine the cited prior art, applicants have not provided any evidence to show that the cited combination does not result in the claimed invention. MPEP states that the arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Additionally, If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Thus, given the teachings of the cited prior art, applicants' arguments that examiner did not articulate why one should combined the teachings of Pacini and Cunningham to modify the teachings of Lambert or Syverson is not persuasive. It is the position of the examiner that a modification of the cited art to arrive at the instant invention flows logically and not based on impermissible hindsight.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1611

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1611

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
December 4, 2009